

SENATE BILL 1466

By McNally

AN ACT to amend Tennessee Code Annotated, Title 63
and Title 68, relative to pain management clinics.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is amended by adding the following as a new section:

Notwithstanding this title or title 68, in the case of a pain management clinic that fails to maintain records when these records would be used to determine if a practice or facility is eligible to be licensed as a pain management clinic in accordance with this part, the penalty for failure to maintain records shall be assessed pursuant to this part, instead of under any other law.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a) An entity or person who operates a pain management clinic without obtaining a license pursuant to this part commits a Class A misdemeanor. Each day of operation without a license constitutes a separate offense.

(b) The commissioner of health may authorize an investigation of any person to the extent necessary to determine if the person is engaged in the unlawful operation of a pain management clinic.

(c) The commissioner may, through the office of the attorney general and reporter, apply for injunctive relief in any court of competent jurisdiction to enjoin any person from committing an act in violation of this chapter. Injunctive proceedings are in addition to, and not in lieu of, all penalties and other remedies prescribed in this chapter.

(d) A person who aids or requires another person to directly or indirectly violate this chapter or rules promulgated pursuant to this chapter, who permits a license issued by the commissioner to be used by any person other than the licensee, or who acts with the intent to violate or evade this chapter or rules promulgated pursuant to this chapter is subject to a civil penalty of not more than one thousand dollars (\$1,000) for each violation. Each day of operation without a license constitutes a separate violation.

SECTION 3. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a) In those cases where the conditions of any pain management clinic are, or are likely to be, detrimental to the health, safety, or welfare of the patient, the commissioner of health has the authority to suspend treatment of any new or existing patients to the clinic pending a reasonably prompt hearing before an administrative judge.

(b) The commissioner is authorized to revoke the suspension of treatment, at any time prior to a hearing, based on information presented to the commissioner showing that such conditions have been and will continue to remain corrected.

(c) Whenever the commissioner suspends the treatment of any new patients, the commissioner shall detail, in a notice to the clinic, the specific violations causing the suspension.

(d) Notice shall detail what conditions are considered detrimental to the health, safety, or welfare of the patients and an explanation of the specific time frame when, and conditions under which, the clinic can reasonably expect the suspension to be lifted.

(e) Within ten (10) days of receiving the notice described in subsection (d), or lesser time frame when deemed necessary by the commissioner to ensure the health, safety, and welfare of clinic patients, a pain management clinic shall submit a corrective action plan to the commissioner delineating the measures to be taken to address violations and associated time frames. If it is deemed by the commissioner to be

necessary to ensure the health, safety, and welfare of clinic patients, the commissioner may require the clinic to take all necessary actions to correct violations immediately.

(f) If the clinic complies with the conditions described in subsection (d), the commissioner shall lift the suspension within the time frame described in subsection (e), unless other conditions exist that warrant an additional suspension or continuation of the suspension. The commissioner has the authority to:

- (1) Continue, revoke, or modify the suspension of treatment;
- (2) Revoke, suspend, or condition the license of the clinic; and
- (3) Enter other orders as the commissioner deems necessary.

(g) During a suspension of treatment pursuant to this section, the commissioner shall appoint one (1) or more special monitors, if the deficiency threatens serious harm to the patients of the clinic. The commissioner may appoint a special monitor or monitors at any other time, if the commissioner has reason to believe that deficiencies exist in a clinic that are detrimental to the direct care of the patients. Whenever the appointment of monitors is utilized pursuant to this section, the commissioner shall appoint a sufficient number of monitors to ensure their presence in the clinic for a minimum of twenty (20) hours per week. The monitors shall observe the operation of the clinic and shall submit written reports periodically to the commissioner on the operation of the clinic. Persons appointed as monitors shall be duly qualified to discharge their responsibilities. While employed as monitors, they shall represent the department with the power to observe and review all of the clinic's operation, with attention to those aspects for which the suspension of admission was imposed. When appointment of a monitor or monitors is mandated by this section, the clinic shall be liable for the costs of the special monitors, until it has been determined that the deficiencies have been corrected. The commissioner may retain a monitor in a clinic after correction to evaluate

the clinic's continued compliance, but such continued monitoring shall be at the expense of the department. The costs of the monitors shall be recoverable as follows:

- (1) Deduction of the amount of the costs from amounts otherwise due from the state to the clinic and to remittance of the amounts to the department;
 - (2) Addition of such costs to the clinic's licensing fee, the renewal of the clinic's license to be contingent upon the prior payment of the costs; or
 - (3) By suit of the department in the circuit or chancery court to recover the costs.
- (h) Judicial review shall be available pursuant to § 4-5-322.

SECTION 4. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following as a new section to be appropriately designated:

- (a) The medical director of each pain clinic shall report annually to the department of health on a form promulgated by the department the following:
- (1) The number of physician assistants and advanced practice nurses who are working in the clinic for each month;
 - (2) The number of pain patients seen by the clinic for each month;
 - (3) The number of patients that have been treated at the clinic who have overdosed;
 - (4) The number of patients being treated for pain at the clinic that have died during the year;
 - (5) Whether the pain clinic is part of or associated with a hospital; and
 - (6) The number of morphine milligram equivalent daily doses (MMEDD) per patient per clinic.
- (b) The department is authorized to promulgate the reporting form, and establish the reporting period and dates for submission.

SECTION 5. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a) On or after January 1, 2017, no person shall operate a pain management clinic unless the person obtains a license from the department and is registered with the state as a certificate holder. No license shall be issued or renewed unless the pain management clinic has been inspected and found to be in compliance by the department. The department is authorized to charge a reasonable fee for any application for a license or certificate.

(b)

(1) Except as provided in subdivision (b)(2), a license shall expire on December 31 of each odd-numbered year.

(2) Every person licensed under this section in this state shall receive from the department a certificate of licensure. Notwithstanding any provision of this title to the contrary, the department shall establish a system of license renewals at alternative intervals that will allow for the distribution of the license workload as uniformly as is practicable throughout the calendar year. Licenses issued under the alternative method are valid for twenty-four (24) months and expire on the last day of the last month of the license period. However, during a transition period, or at any time thereafter when the department determines that the volume of work for any given interval is unduly burdensome or costly, either the licenses or renewals, or both of them, may be issued for terms of not less than six (6) months nor more than eighteen (18) months. The fee imposed for any license under the alternative interval method for a period of other than twenty-four (24) months shall be proportionate to the annual fee and modified in

no other manner, except that the proportional fee shall be rounded off to the nearest quarter of a dollar (25¢).

(3) No renewal application will be accepted after the last day of the month following the license expiration date under the alternative method authorized in subdivision (b)(2).

(c) The department shall inspect each clinic a minimum of one (1) time each year to ensure compliance with this part.

(d) Any certificate holder, in order to lawfully establish, conduct, operate, or maintain a pain management clinic shall obtain a license from the department in the following manner:

(1) The applicant shall submit an application on a form to be prepared by the department, showing that the applicant is of reputable and responsible character and able to comply with the minimum standards for a pain management clinic and with rules lawfully promulgated under this part. The applicant shall also submit any required fees. The application shall contain the following additional information:

(A) The name or names of the applicant or applicants;

(B) The location of the institution;

(C) The name of the medical director, and the identification of any other license or application related to a pain management clinic with which the medical director is associated; and

(D) Other information as the department may reasonably require;

(2) If the commissioner determines that a license for any facility will not be granted, the commissioner shall notify the applicant. The decision of the commissioner shall be final; and

(3) If the commissioner finds that the applicant complies with this part and the rules promulgated under this part, then the commissioner shall recommend and approve the issuance of a license, and a license shall be issued by the department licensing the applicant to operate the facility.

(e)

(1) The commissioner shall promulgate by rule additional licensure requirements that define appropriate health and safety standards necessary to protect the health and welfare of residents.

(2) The commissioner shall promulgate by rule specifying additional financial requirements, such as bonds or liability insurance.

(f) Each license to operate a facility shall expire as provided in subsection (b) and shall become invalid on that date unless renewed. A licensee may renew its license within sixty (60) days following the license expiration date upon payment of the renewal fee in addition to a late penalty established by the commissioner for each month or fraction of a month that payment for renewal is late. A late penalty shall not exceed twice the renewal fee. If a licensee fails to renew its license within sixty (60) days following the license expiration date, the licensee shall reapply for licensure in accordance with the rules established by the commissioner. A license shall not be assignable or transferable, shall be issued only for the premises named in the application, shall be posted in a conspicuous place in the clinic, and may be renewed from year to year.

(g)

(1) The commissioner may suspend or revoke the license issued under this part on any of the following grounds:

(A) A violation of this part or of the rules promulgated pursuant to this part;

(B) The permitting, aiding, or abetting the commission of any illegal act in the facilities;

(C) Any conduct or practice found by the commissioner to be detrimental to the welfare of the patients in the facilities; or

(D) A conviction of any employee of the clinic for an offense involving the sale or dispensing of controlled substances under state or federal law related to the operation of the clinic.

(2) The commissioner may, after a hearing, hold the case under advisement and make a recommendation as to requirements to be met by the facility in order to avoid either suspension or revocation of license or suspension of admissions.

(3) The commissioner shall promulgate rules defining the sanction structure and associated penalties.

(4) The commissioner shall have the authority to place a facility on probation.

(5) The hearing to suspend a license, revoke a license, place a facility on probation, or impose any other sanction, and judicial review of the commissioner's decision, shall be in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(h) On and after July 1, 2016, an owner or operator of a pain management clinic shall not locate or participate in locating a pharmacy in which the owner or operator has an ownership interest in a location that is adjacent to the location of the clinic. Locating a pharmacy in which the owner or operator of a pain management clinic has an

ownership interest adjacent to the clinic shall result in the revocation of the license of the pain clinic.

(i) An employee of a clinic who is under state or federal indictment in this state for an offense involving the sale or dispensing of controlled substances under state or federal law related to the operation of the clinic shall be suspended from employment at the clinic until the indictment is resolved. If convicted of the offense, the employee shall be terminated from employment at the clinic and the commissioner may consider appropriate action under subsection (g).

(j) Any licensee or applicant for license, aggrieved by a decision or action of the department or commissioner pursuant to this part may request a hearing before the commissioner.

(k) The commissioner is authorized to promulgate, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, rules as are necessary to set fees for licensure, renewal of licensure, late renewal fees, and other fees.

SECTION 6. Tennessee Code Annotated, Section 63-1-301, is amended by adding the following as a new subdivision to be appropriately designated:

() "Operator" means the person who is in charge of the actual on-site operation of a pain management clinic;

SECTION 7. Tennessee Code Annotated, Section 63-1-309(d), is amended by deleting the language "twenty percent (20%)" and substituting instead the language "fifty percent (50%)".

SECTION 8. Tennessee Code Annotated, Title 63, Chapter 6, Part 1, is amended by adding the following language as a new, appropriately designated section:

(a) The board of medical examiners shall contract with the department of health to annually inspect pain management clinics, as defined in § 63-1-301, and the locations

of practices of physicians licensed under this chapter in order to assess providers licensed under this title for compliance with chapter 1, part 3 of this title, and the treatment guidelines issued pursuant to chapter 1, part 4 of this title.

(b) Notwithstanding this title and title 9, the board of medical examiners shall pay for the expenses of the inspections to the department of health out of reserves in the account maintained for the board pursuant to § 63-1-137.

SECTION 9. Tennessee Code Annotated, Title 63, Chapter 9, is amended by adding the following language as a new, appropriately designated section:

(a) The board of osteopathic examination shall contract with the department of health to annually inspect pain management clinics, as defined in § 63-1-301, and the locations of practices of physicians licensed under this chapter in order to assess providers licensed under this title for compliance with chapter 1, part 3 of this title, and the treatment guidelines issued pursuant to chapter 1, part 4 of this title.

(b) Notwithstanding this title and title 9, the board of osteopathic examination shall pay for the expenses of the inspections to the department of health out of reserves in the account maintained for the board pursuant to § 63-1-137.

SECTION 10. Tennessee Code Annotated, Section 68-11-1602(7)(A), is amended by inserting the language "pain management clinic;" between the language "residential hospice;" and the language "or nonresidential substitution-based".

SECTION 11. Tennessee Code Annotated, Section 68-11-1602(7)(B)(iii), is amended by deleting the subdivision and substituting instead the following:

(iii) Any premises occupied exclusively as the professional practice office of a physician licensed pursuant to title 63, chapter 6, part 2, and title 63, chapter 9, or dentist licensed by the state and controlled by the physician or

dentist. This exception shall not apply to a physician or physicians operating a pain management clinic;

SECTION 12. Tennessee Code Annotated, Section 68-11-1602, is further amended by adding the following as a new subdivision to be appropriately designated:

() "Pain management clinic" means a pain management clinic as defined in § 63-1-301;

SECTION 13. Tennessee Code Annotated, Section 68-11-1607, is amended by adding the following as a new subsection (n):

(n) Any requirement for a pain management clinic to obtain a certificate of need under this section shall not apply to a hospital and its related outpatient facilities that have been excluded from the application of title 63, chapter 1, part 3, by § 63-1-302.

SECTION 14. Tennessee Code Annotated, Section 68-11-1609(b), is amended by designating the existing language as subdivision (b)(1) and adding the following as a new subdivision (b)(2):

(2)

(A) In order to permit the development of appropriate criteria for evaluating an application for a certificate of need for a pain management clinic, the agency shall issue no certificates of need for new pain management clinics or for services covered under § 68-11-1607 for a pain management clinic until:

(i) The state health planning division has made recommendations with respect to the appropriate criteria that are consistent with the state health plan; provided, that the recommendations for determining the capacity and distribution of

existing healthcare resources shall be derived from the all payer claims database as set forth in § 56-2-125 and shall be provided by the department of finance and administration on request by the division; provided, further, that the information derived from the database shall only be used for this purpose and shall remain confidential; and

(ii) The agency has adopted appropriate criteria for applications for pain management clinics.

(B) The state health planning division shall consult with the bureau of TennCare, the department of health, and the department of mental health and substance abuse services before making recommendations to the agency.

SECTION 15. This act shall take effect on July 1, 2016, the public welfare requiring it.